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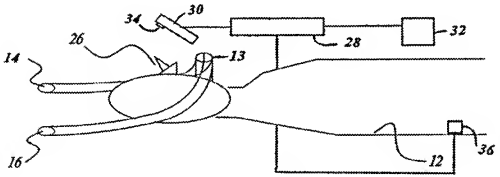
(54) Title: METHOD AND APPARATUS FOR DELIVERING RADIATION THERAPY DURING SUSPENDED VENTILATION



(57) Abstract

The present invention is a method for delivering a radiation therapy to a patient (12) during breath hold when the ventilation is suspended. A computer (28) controls the inhalation, exhalation, suspending the breathing at a predetermined flow direction, and lung volume for a duration which is tolerated by a patient.

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METHOD AND APPARATUS FOR DELIVERING RADIATION THERAPY DURING SUSPENDED VENTILATION

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to a method and apparatus for delivering radiation therapy. More particularly, the present invention relates to a method and apparatus for delivering radiation therapy during suspended ventilation.

2. Discussion

Radiation for the treatment of cancer embodies a variety of risks related to overexposure to healthy tissue. A major concern in increasing the dose to treat cancer is the potential increase in life-threatening complications. This is particularly the case for treatment in the thoracic and upper abdominal regions. Because of respiratory motion, a large margin is needed to ensure proper tumor coverage, which in turn leads to a large volume of healthy tissue being irradiated. For lung treatment, there is a risk of five percent pneumonitis in five years if the whole lung receives more than 1,750 cGy, two-thirds of the lung receives more than 3,000 cGy, and one-third of the lung receives 4,500 cGy. Similar observations have been made for other sites, such as the treatment of focal lesions in the liver.

There are rather difficult tolerances to satisfy if one wants to increase dose. Take, for example, the traditional radiation treatment using AP/PA

(anterior to posterior/posterior to anterior) beam arrangements for lung treatment. Given, for example, a modest lung thickness of 15 cm. Assuming a total lung capacity of 5.0 liters, the total irradiated lung volume is calculated by taking the lung volume around the tumor and subtracting tumor volume. Given a margin of 3 cm around the tumor that is 7 cm in diameter, 45% of the lung will initially be irradiated. Given a margin of 2 cm, 30% of the lung will be irradiated. Given a margin of 1 cm, 18% of the lung will be irradiated. Given a margin of 0.5 cm, 13% of the lung will be irradiated.

In response to concerns regarding over-exposure, there have been intense efforts over the past decade to implement high dose conformal radiation therapy which have led to the development of many new advanced technologies. These advanced technologies include computed tomographic (CT) simulation, three dimensional (3D) treatment planning, computer controlled medical accelerators, multileaf collimators (MLCs), and electronic portal imaging devices (EPIDs). These technologies are becoming increasingly more common, making possible the implementation of new treatment techniques such as intensity modulated radiation therapy. The success of high dose conformal therapy depends critically on treatment accuracy. With more accurate information about the position of a tumor, a tighter treatment margin can be prescribed such that a higher dose can be delivered to the tumor without increasing deleterious complications.

In practice, the treatment margin must account for the width of the beam penumbra, the daily variation in patient setup, and the variation in organ positions between fractions and during a single fraction. Recent

advances have been made to sharpen beam penumbra, reduce daily setup variation and compensate for inter-fraction variation of organ position. (Intra-fraction organ motion associated with breathing, however, remains problematic.) Intra-fraction variations pertain to the changes in the organ shapes and positions during a single treatment fraction. These include the motion of tumors and organs in the thoracic and abdominal regions. In certain procedures for radiotherapy of the thorax, patient breathing has an effect on the procedure. Motion of the lungs and diaphragm can cause displacement of organs and a tumor being treated. Organs and tumors in the thorax and abdomen are known to move by more than 2 cm during the breathing cycle. At present, the 3D imagings used for treatment planning are "static". They do not contain information about the changing tumor positions while the patient breathes. Consequently, a wide margin is used, irradiating a large volume of critical tissue. As a result, limits are placed upon the dose that can be delivered to the tumor. Concern for pulmonary complications has constrained radiation therapy of lung cancer, despite the dismal prognosis of the disease. High dose conformal therapy in the thorax and abdomen is more effective when organ motion due to breathing can be minimized.

There have been different approaches to minimizing respiratory motion. One approach is to have the patient shallowly breathe pure oxygen. Another approach has been through a technique known as "triggering" or "gating" in which the respiration cycle is monitored using an external device such as a spirometer or a string-gauge to turn on the beam only at a certain point in the respiration cycle. A possible component of this technique is to train the

patient to exercise the breath-holding at the appropriate lung volume in order to extend the duty cycle of the beam. A further approach is to use deep inspiration breath holding, during which time the beam is activated.

The optimal delivery of gated or "breath-hold" therapy requires the 3D characterization of dynamic organ and tumor motion such that both beam geometry and "gate" can be optimized. However, this optional approach is not possible with most gated therapy proposals which rely on 2D fluoroscopy. It is also difficult to obtain gated 3D CT scans because of the complexity in machine control. Deep inspiration breath hold can be applied, but the 3D CT scan can only be made in one respiratory position. It is possible that dynamic 3D tomographic images can be made with the Immatron (an ultrafast CT specifically built for cardiac scanning) or using a fast MRI. However, the former approach is prohibitively expensive, while the latter approach produces distortions and complex image fusion is required to provide 3D images.

Accordingly, current approaches to gated therapy rely exclusively on the passive monitoring of respiration, followed by electronic or manual triggering of the beam. However, electronic triggering requires control of the medical accelerator to coordinate with passive respiratory monitoring. This is not readily achieved. On the other hand, manual gating requires the patient to reproducibly get to the same respiratory position. Inevitable variability means that a wider tolerance would need to be set. In addition, the radiation needs to be turned off immediately when the breath-hold creeps out of tolerance. Failure to do so can be serious since gated therapy is likely to employ higher dose rates.

While the above techniques represent various advances in the art, all known methods and devices for the delivery of radiation therapy during suspended ventilation are subject to improvement.

SUMMARY OF THE INVENTION

The method and associated apparatus of the present invention involves attaching a respiration monitor to a patient through a mouth piece that includes air flow valve(s). Computer control provides a measure of the cyclical expiration and inhalation cycle of the patient. When a desired point in the respiration cycle point is reached by the patient, the mouthpiece valve(s) is/are operated to suspend or "freeze" patient breathing at the desired point. In other words, all air flow through the mouth piece is stopped at the desired point. While the valve(s) is/are closed, the patient cannot inhale or exhale. In some cases, several cycles of this breath "freezing" can be used to administer the desired therapeutic radiation dosage. Since the clinician controls the point at which breath freezing occurs, the patient does not have to produce a repeated breathing state. This approach also does not require a complex interconnection between the respiration monitor and radiation therapy equipment. The system is well suited for low cost implementation with a minimal need to interface with the radio therapy manufacturers and equipment.

It is a principal object of the present invention to provide a method and an apparatus which overcome the drawbacks associated with the prior art, including but not limited to those discussed above.

It is another object of the present invention to provide a method and apparatus for eliminating inaccuracy encountered during diagnosis and therapy attributable to movement of body organs resulting from normal breathing.

It is a more specific object of the present invention to provide a method and apparatus for the delivery of radiation therapy during periods of suspended ventilation.

It is another object of the present invention to provide a method and apparatus which allows for CT planning and treatment at a reproducible ventilatory phase.

The above and other objects are achieved in accordance with the principles of the present invention in a method and apparatus for delivering radiation therapy during suspended ventilation.

In one form, the present invention provides a method to suspend ventilation of a patient for the delivery of radiation therapy. The method includes the general step of identifying a specific air flow direction and lung volume. Additionally, the method of the present invention includes the general step of suspending patient ventilation at the specific air flow direction and lung volume. Further, the method of the present invention includes the general step of administering radiation therapy during the suspension of patient ventilation.

BRIEF DESCRIPTION OF THE DRAWINGS

Additional objects and advantages of the present invention will become apparent from a reading of the following detailed description of the preferred embodiments which makes reference to the drawings of which:

Figure 1 is a schematic representation of an active breathing control apparatus embodying the present invention for suspending ventilation for purposes of administering radiation therapy;

Figure 2 is a stylized view showing the active breathing control apparatus of the present invention in operative association with a supine patient;

Figure 3 is a top view of an apparatus constructed in accordance with the teachings of the present invention;

Figure 4 is a graph plotting air flow and lung volume versus time including a period of suspended ventilation for the delivery of radiation therapy;

Figure 5 is a schematic of an alternate embodiment of the apparatus of the present invention;

Figure 6 is a stylized view showing the alternative embodiment of the active breathing control apparatus of the present invention shown in Figure 5 in operative association with a supine patient; and

Figure 7 is a simplified flow chart illustrating the general steps of the method of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring to Figure 1, a schematic diagram of an active breathing control apparatus 10 constructed in accordance with the teachings of the present invention is shown.

The active breathing control apparatus utilizes a ventilator assembly 13. (A suitable ventilator for modification is commercially available from Siemens.) As shown, the apparatus has two "scissors" valves 14 and 16 to monitor and control inhalation and exhalation independently. During normal operation, one of the valves 14 or 16 is always closed while the other is open. With the modifications made pursuant to the present invention, the scissors valves 14 and 16 are interfaced to a personal computer (PC) (not shown). The signals are processed to display the changing lung volume during the breathing cycle. A software utility is implemented to allow the user to specify (1) the point in the breathing cycle for closing both valves 14 and 16, and (2) the duration of the active breath-hold.

The patient 12 is interconnected to the modified ventilator assembly 13 through a subassembly 18 which includes a t-connector 19 which includes a first one-way valve 20 and a second one-way valve 21, a pneumotach 22 and a mouthpiece 23. A first tube 24 connects the scissor valve 14 and a second tube 25 connects to the other scissor valve 16. A nose clip 26 is used to prevent ventilation through the nose. Alternatively, the mouthpiece and nose clip 26 can be replaced by a face mask.

The valves 14 and 16 as well as the pneumotach 22 are connected to a computer 28 which selectively drives each element according to a selected operations program.

Figure 2 illustrates the apparatus of the present invention in relation to a supine patient 12. The ventilator assembly 13 is illustrated in its approximate position in relation to the patient 12. Optionally, a mirror 30 is provided at an angle such as a 45 degree angle for the view of the patient 12. A monitor 32 is preferably provided outside of the treatment room for the operator, while a smaller monitor 34 (or LCD) is optionally provided for viewing by the patient. The monitors 32 and 34 provide a means of continuously displaying the cyclical lung volume trace and the target respiration level while the supine patient is breathing. (The displays need not present the same information.) Each of the monitors 32 and 34 is operatively associated with the computer 28. An abort switch 36 may also be provided for operation by the patient 12 to turn off the radiation machine and open the valve 14 in the event of discomfort.

Figure 3 illustrates is the arrangement of the "scissors" valves 14 and 16 of the active breathing control apparatus 10 within the ventilator assembly 13.

Figure 4 shows the real-time display of the airflow and lung volume for a normal subject during normal breathing. An active breathing control level is also shown.

Figure 5 illustrates an alternate embodiment of the active breathing control apparatus of the present invention. According to this embodiment, a

control apparatus 50 is shown. The apparatus includes a single valve 52 and a pneumotach 54 to monitor and control inhalation and exhalation. The valve 52 and the pneumotach 54 are connected to a computer 55 via lines 56 and 58. The pneumotach 54 is also fluidly connected to a carbon dioxide remover 60 and a millipore filter 61. The carbon dioxide remover 60 may be of the "soda lime" reservoir type, although this is not intended as being limiting.

Figure 6 illustrates the apparatus 50 in operative association with a supine patient 12'. The patient 12' is provided with a noseclip 26.A mouthpiece 13' is used for ventilation. The fluid line 62 is connected with the millipore filter 61 via the fluid tube 62. Optionally, a mirror 64 is provided at an angle such as a 45 degree angle for the view of the patient 12'. A monitor 66 is preferably provided outside of the treatment room for the operator, while a smaller personal monitor (or LCD) 68 is optionally provided for viewing by the patient. Both the monitor 66 and the personal monitor 68 are operatively associated with the computer 55. An abort switch 70 may also be provided for operation by the patient 12' to turn off the radiation machine and open the valve 52 in the event of discomfort.

In comparison to the two valve system set forth previously, the single valve is simpler to operate. However, the two valve system allows the provision of oxygen to the patient via the valve 14. The single-valve modification also avoids the excessive piping used and significantly shortens the length of tubing, thereby greatly reducing the dead-space where air can be compressed. This modified design also improves the precision of volume measurements.

An apparatus is thus provided which allows for the maintenance of breath-holding reproducibility while being as non-intrusive to the patient as possible. In general operation, and the patient lies in a supine position on a rigid surface table-top. Breathing through the nose is restricted by the nose-clip. One end of the bi-directional pneumotachnometer is connected to the patient via the mouthpiece while the other is connected to the scissors valve (one or two valves, depending on the embodiment) which controls airflow. Airflow to and from the patient passes through a "soda lime" reservoir to remove exhaled carbon dioxide in the apparatus of the present invention. Adopting standard respiratory care procedures, a millipore filter is preferably used as a barrier against air-borne contaminants. To ease patient burden, the patient is allowed to nose breathe after each sequence of maneuvers which takes no more than 5 minutes.

Regardless of the embodiment, the apparatus is calibrated for flow and volume measurements based on acceptable hospital standards. The output of the pneumotachnometer is interfaced with a Pentium class PC. The flow signal is processed to calculate the changing lung volume during breathing in real-time. Operation of the scissor valve(s) is done under computer control. Software utilities are implemented to allow the user to select the lung volume and flow direction for closing the valve(s). A separate "arming" utility is engaged and allows the user to specify a time delay for activating the system. For example, zero time delay means that the valve is closed at the immediate next instance when the pre-selected parameters are met. A six-second time delay means adding six seconds to the zero time delay. This

utility helps coordinate application of the apparatus of the present invention for those radiation machines that operate with a short warm-up prior to beam on, such as a CT scanner or an accelerator such as the Elekta-Philips SL-20.

For each patient, an operating reference needs to be reestablished to set the desired respiratory phase for the apparatus. The functional residual capacity (FRC) of the lungs at the end of normal expiration is chosen because it is the most stable lung volume during normal breathing. At FRC, the lungs are at a natural resting position with neutral pressure. At the start of each session, the supine patient will first go through a period of normal breathing to establish a stable breathing pattern. After that, the volume signals at FRC are averaged for one minute, equivalent to 12 to 15 breathing cycles, and then set as the "zero volume reference." With this zero reference, lung volumes at either inspiration or expiration can be specified for the method of the present invention. Provided that the patient has not moved between maneuvers, the zero reference only needs to be established once.

During an initial training session using the present apparatus, the period of active breath hold that can be comfortably maintained by each individual patient is determined. The period is used for subsequent CT scanning and treatment, but is adjusted as necessary. When the supine patient breathes in and out through the apparatus of the present invention, the cyclical lung volume trace and the target level is displayed continuously on a monitor for the user outside of the treatment room. Inside the treatment room, the patient is shown a similar display and the countdown of the breath-hold period via an angled mirror (such as a 45 degree angle). The patient is

also optionally provided with an "abort" switch to turn off the radiation machine and open the valve of the apparatus in case of discomfort. Verbal communication with the patient is maintained throughout the procedure.

Turning now to Figure 7, the method of the present invention for delivering radiation therapy during suspended ventilation will now be described with particular reference to the apparatus itself. Figure 5 is a flow chart illustrating the general steps of the present invention. The method of the present invention includes three general steps.

In a first step 100, a specific air flow direction and lung volume are identified. This identification is conducted with CT scans taken at different phases of suspended ventilation.

In a second step 200, patient ventilation is suspended at the specific air flow direction and lung volume. Ventilation suspension is accomplished by closing the valves. The patient is preferably alerted to impending ventilation suspension to avoid panic.

In a final general step 300, radiation therapy is administered during suspension of patient ventilation. It may be desirable to incorporate mechanisms to discontinue therapy in the event that the patient desires ventilation.

By using the apparatus of the present invention together with the provided method, the positions of the immobilized organs documented in the planning CT can be reproduced during treatment. The treatment margin can therefore be appropriately reduced, enhancing the potential to escalate dose with conformal therapy. Theoretically, CT scans can be acquired according

to the present invention at different respiratory phases. The information can then be analyzed to determine an optimal phase for treatment in terms of the separation of the tumor from other critical organs. A 3D organ "movie" can then be produced for evaluation. However, in practice, it is more important to find a respiratory phase which is most comfortable for the patient to maintain repeated breath-hold during treatment using the present invention and described method. Accordingly, as a default, the expiratory phase near tidal volume is selected, i.e., when the patient begins to exhale after taking in a normal breath. This respiratory phase was preferred by the patients in the preliminary studies, particularly for the longer period of breath-hold. Expiration is chosen because it involves mostly passive lung recoil and may offer some reproducibility advantages. It is anticipated that radiation therapy will be administered over an extended period of days. Generally speaking, the patient, upon returning for treatment, will receive radiation treatments at the previously identified flow direction and lung volume. In certain applications, it may be desirable to conduct follow-up diagnosis to confirm the location of the area identified for treatment.

Example

The following example illustrates the application of the above-described method and apparatus according to the present invention.

Feasibility studies based on CT scanning have been performed on patients with tumors in the thorax and abdomen. Helical CT scans were acquired at different pre-specified phases of the breathing cycle. The same procedures were repeated for a few patients a week to 10 days later. Lung patients could maintain comfortably an active breath-hold of 15 seconds near the end of normal inspiration. When suspended ventilation was applied during deep inspiration, the breath-hold period ranged from 25 seconds to 50 seconds. The suspended ventilation scans had minimal motion artifacts that were common in the planning CT acquired during quiet breathing with a helical scanner. Lung volumes from repeat suspended ventilation scans acquired at the same phase of breath-hold were within 5% of each other. Similar results were observed for the positions of the liver.

Thus, the present invention provides a method and apparatus for suspending ventilation which provides enhanced specificity of diagnosis and treatment.

CLAIMS

We claim:

1. A method for delivering radiation therapy to a patient during suspended ventilation, the method comprising the steps of:

identifying a specific air flow direction and lung volume;

suspending patient ventilation at said specific air flow direction and lung volume; and

administering radiation therapy during the suspension of patient ventilation.

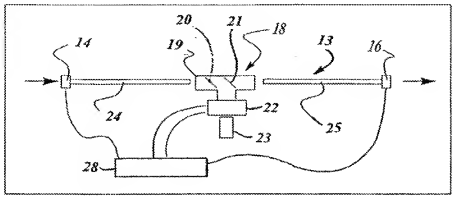

Fig. 1

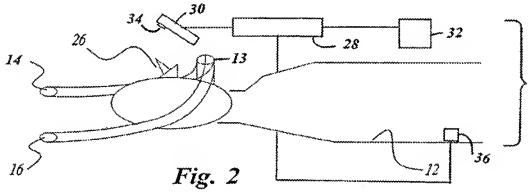

Fig. 2

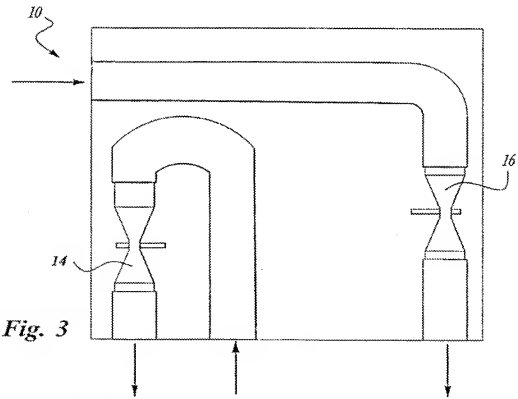

Fig. 3

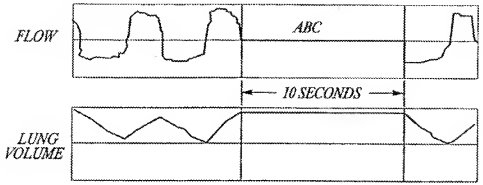

Fig. 4

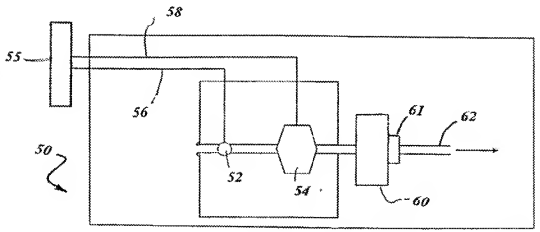

Fig. 5

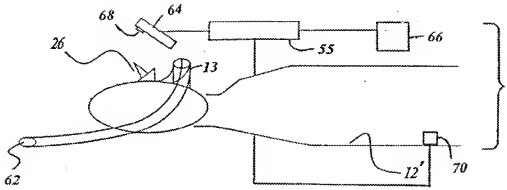

Fig. 6

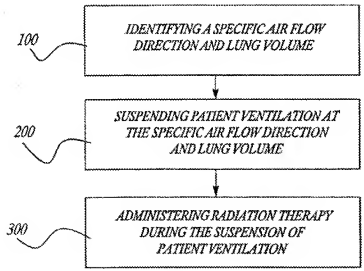

Fig. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/10389

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 16/00

US CL :128/200.24, 204.21, 204.23, 207.14; 604/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/204.23, 204.21, 207.14, 200.24; 604/20

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,558,086 A (SMITH et al) 24 September 1996, col. 6 lines 33-60.	1

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"O"	document referring to an oral disclosure, use, exhibition or other means		
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Date of the actual completion of the international search 14 SEPTEMBER 1998	Date of mailing of the international search report 19 OCT 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer VIRENDRA SRIVASTAVA Telephone No. (703) 308-0959

Form PCT/ISA/210 (second sheet)(July 1992)★

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

	Date of Mailing (*day/month/year*) 19 FEB 2004
Applicant's or agent's file reference VM7012096002	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US03/27552	International filing date (*day/month/year*) 03 September 2003 (03.09.2003)
Applicant VARIAN MEDICAL SYSTEMS, INC.	

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34, chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90 *bis*.1 and 90 *bis*.3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer [signature] Andrew W. Johns Telephone No. (703) 306-0377

Form PCT/ISA/220 (April 2002)

(*See notes on accompanying sheet*)

701209-6003 —
2041/274US —
18762-7001 —

Docket: 18721-6002
Action: ABSTRACT
Date Due: 3-19-04 SPW

Docket: 18721-7001
Action: SUPP. IDS - SEARCH REP.
Date Due: 5-19-2004 OR. SPW

Docket: 701209-6002
Action: RESP. TO SEARCH REPORT
Date Due: 4-19-2004 ORIG. SPW

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference VM7012096002	**FOR FURTHER ACTION**	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US03/27552	International filing date (*day/month/year*) 03 September 2003 (03.09.2003)	(Earliest) Priority Date (*day/month/year*) 03 September 2002 (03.09.2002)
Applicant VARIAN MEDICAL SYSTEMS, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the Report**
   a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
   ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
   b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:
   ☐ contained in the international application in written form.
   ☐ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
2. ☐ **Certain claims were found unsearchable** (See Box I).
3. ☐ **Unity of invention is lacking** (See Box II).
4. With regard to the **title**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows.
5. With regard to the **abstract**,
   ☐ the text is approved as submitted by the applicant.
   ☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. The figure of the drawings to be published with the abstract is Figure No. 1
   ☐ as suggested by the applicant.
   ☐ because the applicant failed to suggest a figure.
   ☒ because this figure better characterizes the invention.
   ☐ None of the figures

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/27552

Box III TEXT OF THE ABSTRACT (Continuation of Item 5 of the first sheet)

NEW ABSTRACT

A method and system for determining the position and orientation of an object (150) is disclosed. A set of markers (104) attached or associated with the object (150) is optically tracked and geometric translation is performed (110) to use the coordinates of the set of markers (104) to determine the location and orientation of their associated object (150).

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/27552

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : G06T 17/00
US CL. : 382/154
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
U.S. : 382/128, 131, 153, 154, 287, 291; 348/94, 142, 600/411, 414, 426, 427

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,300,974 B1 (VIALA et al.) 09 October 2001 (09.12.2001), see column 2, line 49 through column 3, line 46 and column 4, line 5 through column 5, line 39.	1-16, 46
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Y		17-29
Y	US 6,296,613 B1 (EMMENEGGER et al.) 02 October 2001 (02.10.2001), see column 6, line 25 through column 8, line 31.	17-29
X	US 6,434,507 B1 (CLAYTON et al.) 13 August 2002 (13.08.2002), see column 7, line 49 through column 8, line 46.	30-36
X	US 5,771,310 A (VANNAH) 23 June 1998 (23.06.1998), see column 6, line 14 through column 11, line 11.	37-39
X	US 6,348,058 B1 (MELKENT et al.) 19 February 2002 (19.02.2002), see column 2, line 66 through column 4, line 38.	40-45
A	US 4,853,771 A (WITRIOL et al.) 01 August 1989 (01.08.1989), see the entire document	1-46

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
26 January 2004 (26.01.2004)

Date of mailing of the international search report
19 FEB 2004

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (703)305-3230

Authorized officer
Andrew W. Johns
Telephone No. (703) 306-0377

Form PCT/ISA/210 (second sheet) (July 1998)

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended ?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When ? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments ?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

(i) the claim is unchanged;

(ii) the claim is cancelled;

(iii) the claim is new;

(iv) the claim replaces one or more claims as filed;

(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.